

REMARKS

In the Office Action dated July 25, 2005, claims 1-3, 11, 12 and 14-21 are rejected under 35 U.S.C. § 112, second paragraph. Claims 13 is rejected under 35 U.S.C. § 103(a) as being allegedly anticipated by Peiris *et al.* (*Lancet* 361:1319-1325; hereafter "Peiris") or Drosten *et al.* (*New England Journal of Medicine* 348:1967-1976; hereafter "Drosten") or Ksiazek *et al.* (*New England Journal of Medicine* 348:1953-1966; hereafter "Ksiazek"). Claims 1-3 are rejected under 35 U.S.C. § 102(a) as being allegedly anticipated by Genbank locus AY274119. Claim 3 is rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by McSwiggen *et al.* (WO 2004/092383; hereafter "McSwiggen"). Claims 20-21 are rejected under 35 U.S.C. § 102(a) as being allegedly unpatentable over Genbank locus AY273119. Claim 21 is rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over *McSwiggen*. Claims 11, 12 and 14-21 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over *Peiris* or *Drosten* or *Ksiazek*, any of the preceding in view of Genbank locus AY274119. Claims 1, 3, 11, 13-16 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 18, 20, 23, 26, 28, 29, 31, 32, 75, 77, 79, 136-139 and 158 of copending application no. 10/808121. Claims 1-3, 11, 12, 13, 14, and 16, 17 and 19-21 are herein amended. New claims 22-30 are herein added. No new matter has been introduced.

Reconsideration of the present application in view of the foregoing amendments and the remarks below is respectfully requested.

Claims Rejection under 35 U.S.C. § 112

Claims 1-3, 11, 12, 14-21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Office Action states that, in relation to the use of phrase "consisting essentially of", "the specification does not make clear what applicants regard as constituting a material change in the basic and novel characteristics of the invention" and, "[t]herefore, the scope of claims 1-3 is indefinite."

Claims 1-3 are herein amended to read, in a relevant portion, "wherein said nucleic acid molecule is 100 nucleotides or less in length". Support for the amendment can be found, for example, at page 53, lines 25-31, of the present specification.

Accordingly, the rejection of claims 1-3 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

The Office Action further states that claims 11, 12 and 14-21 recited products "having" a recited sequence and that, "[i]n the context of these claims, it is not clear if 'having' is meant to be equivalent to 'comprising', or equivalent to 'consisting of'.

Applicants respectfully submit that neither of claims 20 and 21 recites the term "having" and, therefore, Applicants believe the rejection should have been directed to 11, 12 and 14-19. Accordingly, Applicants' response to this part of the rejection is limited to claims 11, 12 and 14-19.

Claims 11, 12, 14, 16, 17 and 19 are herein amended to more particularly point out and distinctly claim the present invention.

Accordingly, Applicants respectfully request that the rejection of claims 11, 12, 14, 16, 17 and 19 under 35 U.S.C. § 112, second paragraph, be withdrawn.

Claim Rejection under 35 U.S.C. § 102

(1) Claim 13 is rejected under 35 U.S.C. § 102(a) as being allegedly anticipated by *Peiris* or *Drosten* or *Ksiazek*.

Claim 13 is herein amended to recite that the hSARS virus has China Center for Type Culture Collection Deposit Accession No. CCTCC-V200303. This virus was deposited on April 2, 2003 with China Center for Type Culture Collection according to the Budapest Treaty and was accorded an accession number, CCTCC-V200303, as disclosed in U.S. Provisional Patent Application No. 60/459,931 filed April 2, 2003, to which the present application claims priority benefit. Furthermore, the entire genomic sequence of CCTCC-V200303 was disclosed in U.S. Provisional Patent Application No. 60/464,886 filed April 23, 2003, to which the present application also claims priority benefit. Thus, Applicants believe the correct effective date for claim 13 is April 2, 2003, which is earlier than the publication dates of any of the cited references.

Accordingly, applicants believe claim 13 is not anticipated by any of *Peiris*, *Drosten*, or *Ksiazek* and, therefore, the rejection of claim 13 under 35 U.S.C. § 102(a) as being anticipated by *Peiris* or *Drosten* or *Ksiazek* should be withdrawn.

(2) Claims 1-3 are rejected under 35 U.S.C. § 102(a) as being anticipated by Genbank locus AY274119.

Specifically, the Office Action states that “[t]he Genbank entry discloses an isolated nucleic acid which comprises SEQ ID NOs: 2471-2476, thereby meeting each and every limitation of these claims.”

Applicants respectfully traverse the rejection.

Claims 1-3 are herein amended to more particularly point out and distinctly claims the present invention.

Unlike the statement in the Office Action, claims 1-3 as amended recite that an isolated nucleic acid molecule “consists essentially of the nucleic acid sequence of” the recited sequences and that “said nucleic acid molecule is 100 nucleotides or less in length.”

The Genbank entry does not teach or even suggest any specific regions of the AY274119 as recited in claims 1-3 and, therefore, the rejection of claims 1-3 under 35 U.S.C. § 102(a) as being anticipated by Genbank Locus AT274119 should be withdrawn.

(3) Claim 3 is rejected under 35 U.S.C. § 102(e) as being anticipated by *McSwiggen*.

Specifically, the Office Action states that *McSwiggen* teaches a nucleic acid which contains only 3 residues added to applicant's SEQ ID NO:2476.

McSwiggen systemically divides the genomic sequence into about **3,400 sequences** of 19-23 nucleotides in length and simply lists them as the sequences that could be siRNAs with possible efficacies. *McSwiggen* does not disclose at all which sequences out of 3,400 sequences are useful as a probe for the detection assay disclosed in the present application. Listing equally divided genomic sequence is not

much different from simply disclosing the entire sequence of the virus. One skilled in the art is left with choices of about 3,400 sequences to test their applicability as a probe to the detection assay of the present invention, resulting in undue experimentation. Thus, *McSwiggen* is not enabling to be qualified as prior art and does not anticipate claim 3.

Accordingly, Applicants respectfully request that the rejection of claim 3 under 35 U.S.C. § 102(e) be withdrawn.

Claim Rejection under 35 U.S.C. § 103

(1) Claims 20 and 21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Genbank locus AY274119.

Claims 20 and 21 are herein amended to more particularly point out and distinctly claim the present invention. The reference does not disclose any specific regions of the AY274119 as useful for the detection assay of the present invention.

Accordingly, claims 20-21 as amended are not obvious over Genbank locus AY274119 and, therefore, Applicants respectfully request that the rejection of claims 20 and 21 under 35 U.S.C. § 103(a) as being unpatentable over Genbank locus AY274119 be withdrawn.

(2) Claim 21 is rejected under 35 U.S.C. § 103(a) as being unpatentable over *McSwiggen*.

Specifically, the Office Action states that the claim "differs from the reference in requiring the nucleic acid to be in a container."

As discussed in the previous section, *McSwiggen* systemically divides the genomic sequence into about **3,400 sequences** of 19-23 nucleotides in length and simply lists them as the sequences that could be siRNAs with possible efficacies. Listing equally divided genomic sequence is not much different from simply disclosing the entire sequence of the virus and, thus, does not teach a specific sequence useful for the detection assays of the present invention.

Accordingly, Applicants respectfully requests that the rejection of claim 21 under 35 U.S.C. § 103(a) as being unpatentable over *McSwiggen* be withdrawn.

(3) Claims 11, 12 and 14-21 are rejection under 35 U.S.C. § 102(a) as being unpatentable over *Peiris* or *Drosten* or *Ksiazek*, any of the preceding in view of Genbank locus AY274119.

The Office Action specifically states that “[e]ach of the primary references teaches a PCR method for detecting the SARS virus”, that “they differ from the claimed invention in requiring probes and primers from a different segment of the genome” and that “it would have been within the ordinary skill of the art to choose any segment of the genome for probes and primers . . . with reasonable expectation of success.”

Applicants respectfully traverse the rejection.

The objective of the present invention was to establish a highly sensitive RT-PCR assay for detecting SARS-CoV particularly in samples isolated on days 1-3 of disease onset. When such samples were tested with the conventional RT-PCR assays as disclosed in the cited references, only 22% of these samples were shown to have SARS-CoV RNA (see Table 5 at page 75 of the present specification). In order to improve the sensitivity of SARS-CoV RT-PCR detection in the early stage of the illness, the present inventors developed a modified RNA extraction protocol, which doubled the

sensitivity (Table 5). To further improve the detection sensitivity, the present inventors developed the detection methods as recited in claims 11, 12 and 14-19 using the recited specific primers in combination with the specific 5' nuclease probes, which could minimize the false positive rate due to an increase in signal specificity. As shown in Table 5 at page 75 of the present specification, the methods of the present invention significantly improved the sensitivity (80%) and specificity (100%) compared to the conventional RT-PCR assays.

None of the cited references teaches or even suggest the methods and kits recited in present claims 11, 12 and 14-21 and, therefore, these claims are not obvious over the references.

Accordingly, Applicants respectfully request that all the rejections under 35 U.S.C. § 103(a) as being unpatentable over *Peiris* or *Drosten* or *Ksiazek*, any of the preceding in view of Genbank locus AY274119, be withdrawn.

Double Patenting

Claims 1, 3, 11, 13-16 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18, 20, 23, 26, 28, 29, 31, 32, 75, 77, 79, 136-139 and 158 of copending application no. 10/808,121.

Upon allowance of the claims, Applicants will submit a Terminal Disclaimer to obviate the rejection.

New Claims

New claims 22-30 are herein added. Support for the new claims can be found, for example, at page 19, lines 19-20 and page 53, lines 25-31, of the present specification. No new matter has been introduced.

Copending Application

Applicants inform the Examiner that claims 12 and 20 of copending application serial no. 10/807,807 filed March 24, 2005 are relevant to the subject matter of the present application.

Application No.: 10/808,187

Docket No.: V9661.0078

Should there be any deficiency in fees, please charge such fee(s) to Deposit Account No. 50-2215.

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Respectfully submitted,

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